General

Guideline Title

Male and female sterilisation.

Bibliographic Source(s)

Clinical Effectiveness Unit. Male and female sterilisation. London (UK): Faculty of Sexual and Reproductive Healthcare (FSRH); 2014 Sep. 68 p. [469 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Royal College of Obstetricians and Gynaecologists (RCOG). Male and female sterilisation. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2004 Jan. 114 p. (Evidence-based Clinical Guideline; no. 4). [285 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The recommendation grades (A-C, Good Practice Point [GPP]) are defined at the end of the "Major Recommendations" field.

Male and Female Sterilisation: General Information

- Legal advice should be sought if there is any doubt as to whether a person has the mental capacity to consent to a procedure that will permanently remove their fertility. (Grade C)
- Written consent should be obtained from individuals wishing to undergo vasectomy or laparoscopic or hysteroscopic tubal occlusion. (GPP)
- A consent form and clinical record should be used to document an individual's agreement to the procedure, discussion that took place, requests made by the individual, and any information provided. (GPP)

Pre-sterilisation Assessment

- All verbal advice must be supported by accurate, impartial, printed or recorded information (in translation, where appropriate and possible), which the individual requesting sterilisation may take away/download and review before the procedure. (Grade C)
- Counselling and advice on sterilisation procedures should be provided to women and men within the context of a service providing a full range of information about and access to other long-term reversible methods of contraception. This should include information on the

advantages, disadvantages and relative failure rates of each method. (Grade C)
- Both vasectomy and tubal occlusion should be discussed with all men and women requesting sterilisation. (Grade C)
- A history should be taken from all men and women requesting vasectomy or tubal occlusion. Scrotal or bimanual pelvic examination should be carried out either at initial consultation or before commencing the procedure. (Grade C)
- Individuals should be informed that vasectomy carries a lower failure rate, in terms of post-procedural pregnancies, and that there is less risk associated with the procedure than sterilisation carried out by laparoscopy or laparotomy. (Grade C)
- Individuals should be informed of the method of access and tubal occlusion being recommended in their case, the reasons for preferring it over other methods, and the method to be used if the intended procedure cannot be performed. (GPP)
- When a pregnancy occurs while an individual is on a waiting list for sterilisation they should be offered further counselling about future contraceptive choices due to the change in their circumstances. (GPP)
- The operating clinician must ensure that information exchange, history and examination have been completed and must be satisfied that the individual does not suffer from concurrent conditions that may require an additional or alternative procedure or precaution. (Grade C)

Pre-sterilisation Assessment

Advice Post-vasectomy

Men who have undergone vasectomy should be provided with a post-procedural information leaflet that outlines appropriate self-care and instructions. (GPP)

Advice Post-tubal Occlusion

- Women should be provided with information about the method of tubal occlusion undertaken and of any complications that occurred during the procedure. (GPP)
- Women who have undergone tubal occlusion should be provided with a post-procedural information leaflet that outlines appropriate self-care and instructions. (GPP)

Additional Contraception

- Individuals who have undergone vasectomy should be informed of the need to use additional contraception until sterility is confirmed. (GPP)
- Individuals who have undergone hysteroscopic sterilisation with micro-inserts should be informed of the need to use additional contraception until sterility is confirmed. (GPP)

Regret

Additional care must be taken when counselling individuals under the age of 30 years or individuals without children who request sterilisation. (Grade B)

Regret Associated with the Timing of Female Sterilisation

If tubal occlusion is performed at the same time as a caesarean section, counselling and agreement should be given at least 2 weeks in advance of the procedure. (Grade C)

Vasectomy

Anaesthesia

- Vasectomy should be performed under local anaesthesia wherever possible. (Grade B)
- Consideration may be given to warming local anaesthetic to approximately 37°C before infiltration to reduce pain associated with injection. (Grade A)
- Local anaesthetic with or without adrenaline (epinephrine) can be used during vasectomy (outside product licence for bupivacaine with adrenaline). (GPP)
- Local anaesthetic should be administered via infiltration of the subcuticular tissue and by direct injection to the vas deferens. (GPP)
- Local anaesthetic should be administered using a fine-gauge needle to reduce pain. (GPP)

Exposing and Identifying the Vas Deferens

A minimally invasive approach should be used to expose and isolate the vas deferens during vasectomy, as this approach results in fewer early complications in comparison to other methods. (Grade A)

Interruption of the Vas Deferens in Vasectomy

- Cauterisation followed by division of the vas deferens, with or without excision, is associated with the lowest likelihood of early recanalisation (failure) when compared to other occlusion techniques. (Grade A)
- Division of the vas on its own is not an acceptable technique because of the associated failure rate. It should be accompanied by diathermy or ligation and fascial interposition. (Grade A)
- Clips are not recommended for occluding the vas deferens as their use is associated with a potentially high failure rate when compared to other occlusion methods. (Grade A)

Histological Examination

Routine histological examination of the excised portions of vas deferens is no longer recommended. (Grade C)

Post-vasectomy Semen Analysis

- Post-vasectomy semen analysis (PVSA) should be carried out to identify early failure. Additional contraception should be used until azoospermia is confirmed or special clearance given. (Grade B)
- Evidence suggests that 12 weeks post-vasectomy is the optimal timing to schedule the first PVSA. Earlier or later testing is acceptable taking into account that earlier testing increases the probability of additional tests and later testing prolongs the need for additional contraception. (Grade B)
- Postal semen samples can be used for PVSA; however, such samples will not be suitable for the assessment of sperm motility. (GPP)
- Packaging and labelling of postal samples should conform to local laboratory policy/requirements and must comply with Royal Mail standards for the posting of biological specimens. (GPP)
- A routine second PVSA is not required if azoospermia is found in the first sample. (Grade B)
- In a small proportion of men non-motile sperm will persist following vasectomy. In such cases special clearance can be given to cease using additional contraception when less than 100 000 non-motile sperm/ml are observed in a fresh semen sample post-vasectomy. (Grade B)
- If motile sperm are observed in a fresh sample 7 months post-procedure, the vasectomy should be considered a failure. (Grade C)
- If more than 100 000 non-motile sperm/ml are observed in a fresh sample 7 months after vasectomy, clinical judgement and/or local protocols may be used to determine whether or not the procedure should be deemed a failure. (GPP)
- Routine irrigation of the vas deferens does not reduce time to achieve azoospermia and is not recommended. (Grade A)
- Centrifugation is not recommended for establishing the absence of sperm post-vasectomy and may interfere with evaluation of sperm motility. (Grade C)

Intraoperative Complications

Identification of the Vas Deferens

- If a vas deferens cannot be palpated or located, unilateral vasectomy can be carried out following appropriate counselling, and the man advised to comply with additional contraception until sterility is confirmed. These men should be informed of the probability of ipsilateral renal agenesis and may be referred for renal ultrasound. (GPP)
- Where apparent bilateral absence of the vas deferens is encountered, men should be referred to a urology specialist. (GPP)
- If a double or duplicate vas deferens is encountered or suspected, a Doppler ultrasound should be used to determine whether it is a "true" double vas or an ectopic ureter. (GPP)
- Where an anomaly of the vas deferens is suspected, the need for further investigation should be individually assessed by a urology specialist. (GPP)

Bleeding

Health professionals should cauterise or suture any bleeding perivasal and subdermal blood vessels to ensure haemostasis. (GPP)

Pain

If pain is experienced during vasectomy, health professionals should consider the administration of additional anaesthesia/analgesia. (GPP)

Vasovagal Response

- Health professionals should ensure that the clinical room is well ventilated and a comfortable temperature. (GPP)
- Health professionals can consider playing music in the clinical room if the patient wishes, as listening to music has been shown to reduce patient anxiety. (Grade C)

- Health professionals should engage men undergoing vasectomy in conversation and provide reassurance over the course of the procedure. (GPP)

Immediate and Delayed Postoperative Complications

Infection

- The routine use of prophylactic antibiotics is not recommended prior to vasectomy. (GPP)
- Skin cleansing in advance of vasectomy should be undertaken in accordance with local infection control protocols. (GPP)
- The decision to shave the scrotum prior to vasectomy should be based on local infection control/preoperative policies. (GPP)

Early Failure

- Clinicians should modify their technique if overall failure attributable to technical failure, recanalisation and non-compliance with additional contraception is more than 1%. (Grade B)
- The incidence of bleeding, haematoma formation and infection is low and can be further reduced by the adoption of minimally invasive vasectomy techniques. (Grade C)

Long-term Complications

Late Failure

Individuals should be informed that vasectomy has an associated failure rate and that pregnancy can occur several years after vasectomy. The contraceptive failure rate should be quoted as approximately 1 in 2000 (0.05%) after clearance has been given. (Grade B)

Chronic Post-vasectomy Pain

Vasectomy is associated with a risk of postoperative testicular, scrotal, penile or lower abdominal pain that is rarely severe and chronic in some men. (Grade B)

Interventions for Chronic Post-vasectomy Pain

- Non-steroidal anti-inflammatory drugs (NSAIDs) and treatment to alleviate neuropathic pain are common first-line treatment options for chronic post-vasectomy pain (CPVP) and are preferable to surgical treatment, which involves the reversal of vasectomy. (GPP)
- Surgical interventions can be effective in alleviating CPVP, however permanent relief is not achieved in every case. (Grade C)

Prostate and Testicular Cancer

There is no evidence of an increase in testicular cancers associated with vasectomy. The weak association observed in some studies between vasectomy and prostatic cancer is unlikely to be causal. (Grade B)

Cardiovascular Disease

There is no evidence to support an association between vasectomy and cardiovascular disease. (Grade B)

Vasectomy Reversal

Vasectomy reversal involves complex surgery that can result in high postoperative patency rates, but may not result in pregnancy or a return to fertility. (Grade B)

Tubal Occlusion

Approach to the Fallopian Tubes

- Culdoscopy should not be used as a method of approach for sterilisation. (Grade A)
- The laparoscopic approach to the fallopian tubes is quicker to perform and results in less minor morbidity compared to mini-laparotomy. (Grade A)
- All women should be informed of the risks associated with laparoscopy and when this may proceed to laparotomy. (Grade B)
- In some cases laparoscopy/laparotomy may be contraindicated and consideration should be given to other methods. (GPP)

Occlusion Methods

Ligation

- Any effective surgical or mechanical method of tubal occlusion can be used when a minilaparotomy is the method of approach for an interval sterilisation. (Grade B)
- For postpartum sterilisation, both Filshie clips and modified Pomeroy technique are effective. Filshie clip application is quicker to perform. (Grade A)

Mechanical Methods

- Mechanical occlusion of the fallopian tubes by Filshie clips should be the method of choice for laparoscopic tubal occlusion. (Grade A)
- The routine use of more than one Filshie clip is not recommended. (Grade C)

Anaesthesia and Analgesia

- Laparoscopic tubal occlusion can be performed using general, regional or local anaesthesia but general anaesthesia is routinely used in the UK for laparoscopic tubal occlusion. (Grade B)
- Topical application of local anaesthesia to the fallopian tubes may be used whenever mechanical occlusive devices are being applied as short-term postoperative pain is reduced. (Grade A)

Postpartum and Post-abortion Sterilisation

Tubal occlusion should be performed at an appropriate interval after pregnancy wherever possible. Should tubal occlusion be requested either postpartum or post-abortion, women should be made aware of the increased rate of regret and the possible increased failure rate. (Grade B)

Excluding Pregnancy Prior to Surgery

Pregnancy Testing

- A pregnancy test must be performed before sterilisation to exclude the possibility of a preexisting pregnancy. However, a negative test result does not exclude the possibility of a luteal-phase pregnancy. (Grade B)
- Tubal occlusion can be performed at any time during the menstrual cycle, providing that the woman has a negative pregnancy test and is not at risk of luteal-phase pregnancy (no unprotected sexual intercourse [UPSI] in the past 3 weeks). If this is not the case, the procedure should be deferred and contraception used until at least 3 weeks from the last instance of UPSI. (Grade B)

Dilatation and Curettage

During tubal occlusion curettage should not be performed for the purpose of preventing luteal-phase pregnancy. (Grade B)

Stopping Contraception after Laparoscopic Tubal Occlusion

- There is no evidence to support stopping combined hormonal contraception (CHC) use prior to sterilisation or to support the routine use of thromboprophylaxis. (Grade C)
- Women using CHC, the progestogen-only pill (POP) or non-hormonal contraception should be advised to continue their contraceptive method for at least 7 days after laparoscopic sterilisation. (Grade C)
- If laparoscopic sterilisation is scheduled for the hormone-free interval or Day 1 of a cycle of CHC, the hormone-free interval should be omitted or CHC should be restarted, and CHC should be continued for at least 7 days after sterilisation. (Grade C)
- If the progestogen-only injectable or implant is being used, laparoscopic tubal occlusion can be carried out at any time during the period of licensed use without the need for additional contraception. (Grade C)
- The progestogen-only implant can be removed at the time of the procedure or any time following laparoscopic tubal occlusion. (Grade C)
- If a copper intrauterine device (Cu-IUD) or levonorgestrel intrauterine system (LNG-IUS) is *in situ* prior to sterilisation, this should be retained and removed at least 1 week after laparoscopic tubal occlusion. (Grade C)

Failure of Tubal Occlusion

- Late failures resulting in a pregnancy can occur any time after tubal occlusion. (Grade B)
- The lifetime risk of laparoscopic tubal occlusion failure, using a mix of occlusion methods, is estimated to be 1 in 200. (Grade B)
- The longest period of available follow-up data for the most commonly used method in the UK, the Filshie clip, suggests a failure rate of 2–3 per 1000 procedures at 10 years. (Grade B)

Ectopic Pregnancy

- Women should be informed that if tubal occlusion fails, the resulting pregnancy may be ectopic. (Grade B)
- Women should be informed about symptoms of ectopic pregnancy, and the possibility of ectopic pregnancy should be considered in women who have undergone sterilisation and present with abdominal pain, especially in connection with missed periods. (GPP)

Hysteroscopic Sterilisation

Anaesthesia and Analgesia for Hysteroscopic Sterilisation

- There is insufficient evidence to recommend the routine use of oral NSAIDs or intravenous sedation for hysteroscopic sterilisation. The use of such pharmacological agents should be based on clinical judgement. (Grade A)
- Local anaesthesia is not routinely required prior to hysteroscopic sterilisation as it does not alleviate pain associated with the placement of micro-inserts into the fallopian tubes. However, local anaesthesia should be used when dilatation of the cervix is necessary to aid passage of the hysteroscope into the uterine cavity. (Grade A)

Insertion of the Micro-inserts

- The incidence of unsuccessful placement of intra-fallopian implants is reported as ranging between 0% and 19%, following up to two attempts in an outpatient setting. (Grade B)
- The likelihood of successful micro-insert placement is increased if the procedure is scheduled during the proliferative phase of the menstrual cycle. (Grade B)
- Clinicians should undergo a period of supervised training to become proficient in the hysteroscopic insertion of micro-inserts. (Grade C)
- Following sterilisation via hysteroscopy and the insertion of intra-fallopian micro-inserts, additional contraception must be used until either successful insert placement and/or tubal occlusion are confirmed, depending upon the confirmatory test employed. (Grade B)
- Hysteroscopic sterilisation may be safely and effectively undertaken when intrauterine contraception is already *in situ* (outside the terms of the manufacturer's instructions for use). Women should be advised to use additional contraception or abstain from intercourse for 7 days before the procedure in case the intrauterine device needs to be removed to gain access to the fallopian tubes. (GPP)

Intraoperative Complications with Tubal Micro-inserts

Hysteroscopic sterilisation via the placement of intra-fallopian micro-inserts is associated with a low level of intraoperative complications in a minority of patients. (Grade B)

Postoperative Complications of Hysteroscopic Sterilisation

- Hysteroscopic sterilisation via the placement of intra-fallopian micro-inserts is associated with a low level of postoperative complications. The majority of post-procedural adverse events are self-limiting, with most women able to return to daily activities 1–2 days following the procedure. (Grade B)
- Hysteroscopic sterilisation with micro-inserts is contraindicated if there is documented proven patch test for nickel allergy. (GPP)

Post-procedure Imaging Following Micro-insert Placement

- A confirmatory imaging test should be undertaken 3 months after the insertion of intra-fallopian micro-inserts. This may be via X-ray or transvaginal ultrasound scanning (TVUSS) in the first instance, followed by hysterosalpingogram (HSG) in selected patients where X-ray/TVUSS cannot confirm satisfactory placement. (Grade B)
- HSG should be used as a first-line test where the hysteroscopic procedure was considered suboptimal, according to local protocols. (Grade B)
- HSG can be used as a routine test to confirm tubal occlusion following insertion of intra-fallopian micro-inserts. (Grade B)
- Women who do not attend for confirmatory testing should be informed that they need to continue using additional contraception until tubal occlusion is confirmed. (GPP)

Training Issues in Post-procedure Imaging of Micro-inserts

Training in interpretation and performance of confirmatory imaging techniques specifically for sterilisation using Essure is essential, as a number of pregnancies have been attributed to the misinterpretation of images. (GPP)

Efficacy of Micro-inserts

Available evidence suggests that tubal occlusion by intra-fallopian micro-insert has a low associated failure rate of approximately 1 in 500 at 5 years of follow-up; this includes cases where luteal-phase pregnancy or non-adherence with post-procedural instructions was documented. (Grade

B)

Patient Satisfaction with Hysteroscopic Sterilisation

Available evidence suggests that the use of intra-fallopian micro-inserts for tubal occlusion is a procedure that is well tolerated by the majority of women and results in good long-term satisfaction in terms of comfort and tolerance of the insert. (Grade B)

Hysteroscopic Sterilisation and Other Procedures

Endometrial Ablation

Limited available evidence suggests that intra-fallopian micro-insert insertion can be carried out in combination with endometrial ablation. (Grade C)

Long-term Complications of Female Sterilisation

Ovarian Cancer

Tubal occlusion is not associated with an increased risk of ovarian cancer. Evidence suggests that the procedure may have a protective effect against developing ovarian cancer that persists over time. (Grade A)

Breast Cancer

There is no available evidence of an association between tubal occlusion and breast cancer risk. (Grade A)

Cervical and Endometrial Cancer

Available evidence suggests that there is no association between tubal occlusion and cervical or endometrial cancer risk. (Grade B)

Menstrual and Gynaecological Symptoms

- There is no evidence that tubal occlusion results in significant changes to hormone levels. (Grade B)
- Evidence suggests that there is an association between tubal occlusion and an increased risk of subsequent hysterectomy but there is no evidence of causation. (Grade B)
- Women may report worsening menstrual symptoms following tubal occlusion but there is no evidence to suggest a causal effect. (Grade B)

Female Sterilisation Reversal

- Fallopian tube re-anastomosis following sterilisation can result in high postoperative patency rates, but may not result in pregnancy or a return to fertility. (Grade B)
- To date, reversal of sterilisation with micro-inserts cannot be achieved via fallopian re-anastomosis, therefore consideration should be given to *in vitro* fertilisation. (GPP)

Definitions:

Grading of Recommendations

A: Evidence based on randomised controlled trials

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point: Where no evidence exists but where best practice is based on the clinical experience of the guideline group

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Unintended pregnancy

Guideline Category

Counseling

Management

Prevention

Clinical Specialty

Family Practice

Internal Medicine

Nursing

Obstetrics and Gynecology

Urology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To provide clinical guidance on elective male sterilisation (vasectomy) and female sterilisation (tubal occlusion)

Target Population

Men and women who consent to sterilisation

Interventions and Practices Considered

General Information

1. Documentation (legal advice and written consent form)
2. Pre-sterilisation counseling and alternative contraceptive options (verbal and printed)
3. Patient history and physical examination
4. Preoperative same-day pregnancy test (females)
5. Assessment for concurrent conditions which may require an additional or alternative procedure or precaution
6. Post-procedural information leaflets

7. Use of additional contraception until sterility is confirmed
8. Additional consideration for patients under 30 years of age, without children or sterilisation with caesarean section (regret)

Treatment of the Male Patient (Vasectomy)

1. Local anaesthesia (warming of anaesthetic)
2. Minimally invasive approach to expose and isolate the vas deferens
3. Cauterisation followed by division of the vas deferens (with or without excision), division of the vas accompanied by diathermy or ligation and fascial interposition
4. Post-vasectomy semen analysis (PVSA) (12 weeks)
5. Special clearance to discontinue contraception (in men where non-motile sperm persist after vasectomy)
6. Management of intraoperative complications (referral to urology specialist if needed)
7. Management of postoperative complications, including pain
8. Sterilisation reversal information

Treatment of the Female Patient (Tubal Occlusion)

1. Laparoscopy, mini-laparotomy, and laparotomy for access to the fallopian tubes
2. Filshie clips, modified Pomeroy technique for postpartum sterilisation
3. Mechanical tubal occlusion
4. Topical local anaesthesia to the fallopian tubes
5. Hysteroscopic sterilisation
    - Insertion of intra-fallopian micro-inserts
    - Post-procedure imaging (X-ray, transvaginal ultrasound scanning, hysterosalpingogram)
6. General anaesthesia and local anaesthesia (as indicated)
7. Continuation of contraception after laparoscopic tubal occlusion
8. Sterilisation reversal information

Note: The following procedures were considered but not recommended, or there was no supporting evidence: division of the vas deferens on its own, clips for occluding the vas deferens, routine histological examination of the excised portions of vas deferens, routine second PVSA if azoospermia is found in the first sample, routine irrigation of the vas deferens, centrifugation for establishing the absence of sperm post-vasectomy, routine use of prophylactic antibiotics, culdoscopy, routine use of more than one Filshie clip, dilatation and curettage to prevent luteal phase pregnancy, stopping combined hormonal contraception (CHC) use prior to sterilisation or the routine use of thromboprophylaxis, oral non-steroidal anti-inflammatory drugs (NSAIDs) or intravenous sedation for hysteroscopic sterilisation.

Major Outcomes Considered

- Success and failure rates of vasectomy and tubal occlusion (e.g., post-procedure pregnancy rate)
- Ease of reversibility
- Ectopic pregnancy rate
- Complication rates (e.g., risk of visceral injury)
- Pain and/or discomfort
- Patient satisfaction
- Postoperative menstrual irregularities
- Morbidity & mortality

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Evidence is identified using a systematic literature review and electronic searches are performed for: MEDLINE (Ovid version) (1996–2014); EMBASE (1996–2014); PubMed (1996–2014); The Cochrane Library (to 2014) and the US National Guideline Clearinghouse (NGC). The searches are performed using relevant medical subject headings (MeSH), terms and text words. The Cochrane Library is searched for relevant systematic reviews, meta-analyses and controlled trials relevant to sterilisation. Previously existing guidelines from the Faculty of Sexual and Reproductive Healthcare (FSRH) (formerly the Faculty of Family Planning and Reproductive Health Care), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO) and the British Association for Sexual Health and HIV (BASHH), and reference lists of identified publications, are also searched.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Not Given)

Rating Scheme for the Strength of the Evidence

Not stated

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Selected key publications are appraised using standard methodological checklists similar to those used by the National Institute for Health and Care Excellence (NICE). All papers are graded according to the Grades of Recommendations Assessment, Development and Evaluation (GRADE) system. Recommendations are graded using a scheme similar to that adopted by the Royal College of Obstetricians and Gynaecologists (RCOG) and other guideline development organisations (see the "Rating Scheme for the Strength of the Recommendations" field). The clinical recommendations within this guidance are based on evidence whenever possible. Summary evidence tables are available on request from the Clinical Effectiveness Unit (CEU). The process for the development of CEU guidance is detailed on the Faculty of Sexual & Reproductive Healthcare (FSRH) Web site (www.fsrh.org). The methods used in the development of this guidance (CEU Process Manual version 2.0) have been accredited by National Health Service (NHS) Evidence.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Clinical Effectiveness Unit (CEU) guidance is developed in collaboration with the Clinical Effectiveness Committee (CEC) of the Faculty of Sexual & Reproductive Healthcare (FSRH). The CEU guidance development process employs standard methodology and makes use of systematic literature review and a multidisciplinary group of professionals. The multidisciplinary group is identified by the CEU for their expertise in the topic

area and typically includes clinicians working in family planning, sexual and reproductive health care, general practice, other allied specialities, and user representation. In addition, the aim is to include a representative from the FSRH CEC, the FSRH Meetings Committee and FSRH Council in the multidisciplinary guideline development group.

Details of the methods used by the CEU in developing this guidance are outlined in Appendix 1 of the original guideline document and in the CEU section of the FSRH website (see the "Availability of Companion Documents" field). Recommendations within this document are based on the best available evidence and the consensus opinion of experts.

Rating Scheme for the Strength of the Recommendations

Grading of Recommendations

A: Evidence based on randomised controlled trials

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point: Where no evidence exists but where best practice is based on the clinical experience of the guideline group

Cost Analysis

A limited volume of evidence was identified that sought to examine the cost effectiveness of hysteroscopic compared to laparoscopic sterilisation. The majority of this evidence utilised data from the USA health care system, meaning that no direct comparison with the UK was possible. However, there was consensus that the cost of the micro-inserts is the largest cost associated with the procedure; the retail price of the Essure micro-inserts in the USA is reported to be US $1299. The prices for the micro-insert in the UK as quoted by the manufacturer are given in Table 2 in the original guideline document.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Drafts are reviewed by a selected Multidisciplinary Group (MDG), the Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Effectiveness Committee (CEC) and independent peer reviewers before a draft is prepared for public consultation.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Safe and effective use of sterilisation procedures for women and men

Potential Harms

Vasectomy

- A number of case reports were identified that reported vas deferens anomalies as a potential intraoperative complication of vasectomy.
- Excessive bleeding may also occur as an intraoperative complication of vasectomy.
- Immediate and delayed postoperative complications:
  - Bleeding and haematoma
  - Infection
  - Early failure
- Long-term complications:
  - Late failure
  - Chronic post-vasectomy pain
- A single, small-scale, case-control study was identified which reported that vasectomy may be associated with primary progressive aphasia, a form of dementia, due to autoimmune reactions (i.e., anti-sperm antibodies). However, a recently published study did not observe such an association.
- While there are no recognised risk factors for urolithiasis (renal stones) attributable to vasectomy, two studies suggest that there is a higher incidence of urolithiasis in men who had a vasectomy.

Tubal Occlusion Procedures

- Major complications associated with laparoscopic surgery are injuries to the bowel, bladder and blood vessels that require laparotomy.
- Studies that examined the placement of the Essure micro-insert have reported a low level of intraoperative complications, such as vasovagal response and pain during the procedure.
- Postoperative complications of hysteroscopic sterilisation that were reported as affecting a minority of patients include nausea, stomach cramps, dyspareunia, urinary tract infection, nickel allergy, vaginal discharge and pelvic inflammatory disease (PID).

Contraindications

Contraindications

- The Essure micro-insert manufacturer lists the following contraindications for use:
  - Uncertainty about ending fertility
  - Pregnancy or suspected pregnancy
  - Delivery or abortion of a second-trimester pregnancy <6 weeks before micro-insert insertion
  - Active or recent pelvic infection
  - Untreated acute cervicitis
  - Unexplained or severe vaginal bleeding
  - Known or suspected gynaecological malignancy
  - Known abnormal uterine cavity or fallopian tubes that impairs visualisation of the tubal ostia or that makes cannulation of the proximal fallopian tube difficult/impossible
  - Allergy to contrast media used for hysterosalpingogram (HSG)
  - Women taking corticosteroids
- Hysteroscopic sterilisation with micro-inserts is contraindicated if there is documented proven patch test for nickel allergy.
- Local anaesthesia is contraindicated when there is a history of an allergy to local anaesthetic and/or the presence of a medical co-morbidity where it is clinically inappropriate to use a local anaesthetic.
- Contraindications for laparoscopy can include diabetes mellitus or other medical disease.

Qualifying Statements

Qualifying Statements

This document provides clinical guidance on elective male sterilisation (vasectomy) and female sterilisation (tubal occlusion). It is intended for any health professional or service that undertakes vasectomy and/or tubal occlusion in the UK as well as those who refer individuals for either procedure. The guidance does not include cost-effectiveness analysis of sterilisation in relation to other contraceptive methods. Recommendations made herein are intended to inform practice in the UK and therefore methods and practices not utilised in the UK are not included.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Audit Criteria/Indicators

Quick Reference Guides/Physician Guides

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Clinical Effectiveness Unit. Male and female sterilisation. London (UK): Faculty of Sexual and Reproductive Healthcare (FSRH); 2014 Sep. 68 p. [469 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

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Guideline Developer(s)

Faculty of Sexual and Reproductive Healthcare - Professional Association

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Guideline Committee

Clinical Effectiveness Unit

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Financial Disclosures/Conflicts of Interest

Declared Interests

Professor John Guillebaud receives consultancy and lecture fees from pharmaceutical companies, including Bayer, Consilient, Glaxo, HRA Pharma, Janssen and MSD.

Professor Michael Labrecque accepted stock options for Contravac Inc. in return for conducting a study of SpermCheck. Part of his income is obtained by performing vasectomies.

Ms Pauline Bagnall has received exhibition sponsorship from Lilly and Pfizer.

Dr Kay McAllister has received payment from pharmaceutical companies for educational meetings.

Dr Stephen Searle has received sponsorship from pharmaceutical companies for educational events.

Dr Sebastiaan Veersema, Mr Andrew Baxter and Mr T Justin Clark have been consultants and Essure trainers for Bayer.

Dr Sue Milne's department receives endowment funds from Bayer for acting as a training centre for Essure.

Dr Farah Chaudhry has acted as a speaker at events sponsored by Bayer and MSD and was a member of an advisory board for Bayer.

Mr T Justin Clark is a scientific editor for BJOG and receives an honoraria for each article edited.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Royal College of Obstetricians and Gynaecologists (RCOG). Male and female sterilisation. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2004 Jan. 114 p. (Evidence-based Clinical Guideline; no. 4). [285 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the Faculty of Sexual and Reproductive Healthcare Web site .

Print copies: Available from the Faculty of Sexual and Reproductive Health Care, 27 Sussex Place, Regent's Park, London NW1 4RG.

Availability of Companion Documents

The following are available:

- Faculty of Sexual and Reproductive Healthcare Clinical Guidance. Male and female sterilisation: summary of recommendations. London (UK): Faculty of Sexual and Reproductive Healthcare; 2014 Sep. 20 p. Electronic copies: Available from the Faculty of Sexual and Reproductive Healthcare (FSRH) Web site .
- Faculty of Sexual and Reproductive Healthcare: Clinical Effectiveness Unit. Framework for guideline development. London (UK): Faculty of Sexual and Reproductive Healthcare; 2014 Sep. 37 p. Electronic copies: Available from the FSRH Web site .

In addition, questions for continuing professional development, auditable outcomes, a table on the failure rate of various contraceptive methods and criteria for excluding pregnancy are available in the original guideline document .

Patient Resources

None available

NGC Status

This summary was completed by ECRI on January 8, 2001. It was verified by the guideline developer as of February 6, 2001. This NGC summary was updated by ECRI on September 9, 2005. The updated information was verified by the guideline developer on October 11, 2005. This summary was updated by ECRI Institute on December 9, 2014. This summary was updated by ECRI Institute on September 21, 2015 following the U.S. Food and Drug Administration advisory on non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs).

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